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Guidance for the Reregistration of Pesticide Products Containing Picloram as the Active Ingredient

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GUIDANCE FOR THE REREGISTRATION OF MANUFACTURING-USE AND CERTAIN END-USE PESTICIDE PRODUCTS

CONTAINING

PICLORAM

(005101)

CASE NUMBER 096

CAS 2545-60-0

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

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This document contains information regarding the reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA sec. 3(g)) directs EPA to reregister all pesticides as expeditiously as possible.

To carry out this task, EPA has established the Registration Standards program, which will review all pesticide products containing active ingredients first registered before January 1, 1977. Pesticides will be reviewed in use clusters which have been ranked to give earliest review to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. EPA's reassessment results in the development of a regulatory position, contained in a Registration Standard, on each pesticide and its uses. The Agency may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide will not result in adverse effects on the environment.

The scientific review, which is not contained in this Guidance Package but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the end use (formulated) products that contain the active ingredient. If we have serious concerns, we will address end use products as part of the Registration Standards program and will propose regulatory actions to the extent necessary to protect the public.

EPA has the authority under FIFRA sec. 3(c)(2)(B) to require registrants to submit data that will answer our questions regarding the hazard that may result from the intended use of a pesticide. Although sec. 3(c)(2)(B) provides that all registrants are responsible for these data, the Agency generally imposes generic data requirements only on the registrants of of the manufacturing use products (basic suppliers of the active ingredient). End use producers who do not qualify for the formulator's exemption* are also required to submit these data.

An end use producer who wishes to qualify for the formulator's exemption may change his source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. An end use registrant may do so by submitting a new Confidential Statement of Formula, EPA Form 8570-4, identifying the registered source of the active ingredient, to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to cancel the registration of any of your products subject to the requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document. If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product which does not comply with the requirements set forth in this Guidance Document.

You are reminded that FIFRA sec. 6(a)(2) requires you to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

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*The formulator's exemption applies to a registrant of an end use product if the source of his active ingredient(s): (1) is a registered product and (2) is purchased from a source which does not have ownership in common with the registrant's firm.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End use products of registrants who also produce a manufacturing use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing use product(s). Such end use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing use products registered by any company end use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

I. REGULATORY POSITION AND RATIONALE

1. INTRODUCTION

This chapter describes the regulatory position of the Environmental Protection Agency ("the Agency") on picloram based on an evaluation of all registered manufacturing-use products (MP's) containing picloram as the sole active ingredient. Future requests for registration of substantially similar products will be covered by this standard. Dissimilar products will require amendments to the standard. This document provides the rationale for the Agency's position and the criteria for registration. It also discusses labeling requirements for both MP's and end-use products (EP's) and tolerances.

In developing its regulatory position, the Agency determines whether available data indicate that a pesticide has met the criteria for adverse effects found in § 162.11(a) of Title 40 of the U.S. Code of Federal Regulations (CFR). Pesticides meeting these criteria are candidates for a Special Review, an intensive risk/benefit analysis which is a modification of the Rebuttable Presumption Against Registration (RPAR) process. The Agency's determination as to whether any criterion has been met and its rationale for any regulatory action are summarized in the regulatory position of this standard.

2. DESCRIPTION OF CHEMICAL AND USE PROFILE

Picloram is the accepted common name for 4-amino-3,5,6-trichloropicolinic acid which is manufactured solely by the Dow Chemical Company. Formulations of picloram are sold by the Dow Chemical under the trade name TORDON* and GRAZON and by Union Carbide under the trade name AMDON. The Chemical Abstracts Service (CAS) Registry number is 1918-02-1 and the Office of Pesticide Programs' Internal Control Number (EPA Shaughnessy Number) is 005101.

Technical picloram is a damp powder substance, off-white to brown in color, with a chlorine-like odor and a melting point of 215°C. Picloram is stable in both acidic and basic media. It is subject to photodecomposition by ultraviolet radiation in aqueous solution. At 25°C pure picloram is soluble in water at 0.043 grams per 100 milliliters. The vapor pressure of picloram is 6.2×10^{-7} mm at 35°C and 1.1×10^{-6} mm at 45°C. The empirical formula for picloram is $C_6H_3Cl_3N_2O_2$.

Formulations of picloram include potassium and amine salts with the potassium and triisopropanolamine salts being the most commonly used. Liquid product concentrations of picloram range from 0.25 to 2 pounds acid equivalent per gallon while pelleted formulations of picloram range from 2 to 10 percent acid equivalent by weight. There are nine EPA registered products currently on the market that either contain picloram as their sole active ingredient or contain mixtures of picloram and a phenoxy herbicide.

3. REGULATORY POSITION AND RATIONALE

Based on a review and evaluation of all the available data and other relevant information on picloram, the Agency has made the following determinations:

1. The Agency is requiring precautionary label statements advising against the use of picloram in very permeable i.e., well-drained soils such as karst limestone and loamy sands. The Agency requires the registrants to conduct groundwater monitoring studies. All picloram products are currently classified as restricted use pesticides. This classification will remain in effect with the publication of this Standard.

   Rationale: Picloram has been found in groundwater and surface water in West Virginia and was the subject of a public hearing in that state to determine how picloram entered well water that was used to irrigate a greenhouse causing the owner to lose most of his ornamental business. Water contamination and the high degree of phytotoxicity were the basis for classifying picloram for restricted use in 1978. The precaution against use in permeable soils will help prevent such incidents in the future. The Agency has designated for further study, certain chemicals including picloram which may have a potential to enter groundwater supplies in the United States based on such factors as chemical structure, solubility and use patterns. Groundwater monitoring studies are needed to determine the degree to which picloram leaches in different soils.

2. The Agency is granting no new tolerances pending receipt and review of significant toxiological studies.

   Rationale: The established tolerances for picloram are not supported by the data now available to the Agency. Until significant toxicological studies are submitted and reviewed and it is determined whether there are concerns, the Agency cannot consider any new petitions for tolerances. If the toxicological studies indicate that additional residue data are required, an assessment of existing tolerances and new tolerance petitions will be made once these data are reviewed.

3. The Agency is requiring additional wildlife tests on technical picloram in order to complete a hazard evaluation. The Agency is requiring all manufacturing-use products to bear revised environmental hazard statements reflecting the pesticide's toxicity to fish and wildlife.

   Rationale: Based on studies available to assess hazards to wildlife and aquatic organisms picloram appears to be moderately toxic to cold water fish (trout) and slightly toxic to warm water fish (catfish, bluegill). However, chronic studies on lake trout suggest that low concentrations of picloram will adversely affect the rate of yolk sac absorption and growth of fry. The Agency is requiring additional tests on technical picloram in order to complete a hazard evaluation, and a field monitoring study to determine concentrations of picloram in runoff water and sediment, leachate, groundwater, and in water and sediment of receiving aquifers. Updated label precautions required by this Standard should reduce the hazard to fish and other wildlife.

4. The Agency is requiring development of analytical methods for metabolite residues in plant and animal samples and data on storage stability.

   Rationale: Until now, the residue of concern in plants was picloram. This is no longer the case. The concern now includes picloram and its metabolites 4-amino-2,3,5-trichloropyridine and 4-amino-3,5-dichloro-6-hydroxy-picolinic acid. The metabolism of picloram in animals is only partially understood. No metabolites were found in animals, and animals differ from plants in this respect. It is not known if the metabolites were not looked for, were nondetectable, or were not formed in animals. A metabolism study is needed in which ^{14}C ring labeled picloram and its metabolites (in proportions simulating the terminal residues in feed items) are fed to a large animal (the cow) and to the hen, to determine their carryover, free or conjugated form, to tissues, milk and eggs. The need to include these metabolites in tolerances for meat, milk, poultry and eggs, is deferred until the results of such a study are evaluated. All of the described methods are acceptable for the collection of data on residues of intact picloram in plant and animal substrates. Methods are available and acceptable for enforcement, where it concerns picloram alone. The Agency needs to know if these methods also determine residues of picloram and its metabolites free or conjugated in plant and animal substrates (assuming these are shown to be present in animals by metabolism studies). Thus new methodology to determine residues of these previously undetermined entities may be needed.

5. The Agency is requiring oncogenicity data and is requiring the registrant to limit the hexachlorobenzene (HCB) levels in technical picloram to 200 ppm.

   Rationale: The Agency has determined that some studies on long term effects performed by Industrial Bio-Test Laboratories (IBT) were invalid due to improper laboratory practices. In addition, an NCI oncogenicity study on rats and mice fed picloram was negative for oncogenic effects except in the female rats treated at 743 mg/kg day; the effects observed were increased incidences of liver neoplastic nodules. However, the study has drawn criticism because it was conducted in the same room as other tested chemicals which have been shown capable of producing the same lesions. A new replacement study in rats is close to completion. Other chronic and subchronic studies do not exhibit oncogenic effects. A multigeneration reproduction study has produced a NOEL of 3,000 mg/kg. Teratology data on rats exhibit only slight fetotoxicity at 500 mg/kg, the lowest dosage tested. A second species teratology study in the rabbit is close to completion.

Studies have shown that hexachlorobenzene, a contaminant of picloram, is a carcinogen in several species of rodent. Based on this information the Agency conducted a risk assessment and has estimated the dietary cancer risk to the general public of HCB in the fat and milk of cattle fed picloram treated grass to be 4.6×10^{-8} to a 70 kg adult and 1.4×10^{-7} to a 10 kg child. These risk estimates are based on 200 ppm of HCB in currently registered technical picloram. The Agency has concluded that this risk is acceptable. The Agency will impose a maximum limitation of 200 ppm of HCB in technical picloram and is requiring the registrant to submit a revised confidential statement of formula to reflect this required limit.

6. The Agency is requiring data on technical picloram for nontarget area phytotoxicity.

   Rationale: Picloram is highly phytotoxic, easily absorbed by roots and foliage. In soils not subject to leaching it is very persistent with phytotoxicity being detected in some cases well over one year after application. The Agency has determined that damage to nontarget plants is occurring. Phytotoxicity data will be required because the Agency is unable to ascertain whether this damage is a result of applicator error, misuse, drift, leaching, runoff or persistence. In addition, the Agency has contacted the Department of Interior's Office of Endangered Species (OES) to request a biological opinion for picloram on non crop sites. OES has already provided the Agency with biological opinions on rangeland pesticides and forest pesticides. Picloram was included among the pesticides evaluated in both of these clusters. For these clusters, OES listed a number of endangered plants that could be jeopardized when picloram is used within their habitat. OES concluded "As a reasonable and prudent alternative to preclude jeopardy, these chemicals should not be used within or adjacent to habitats of these plants." The Agency may amend this Standard to reflect the OES recommendations once the required data have been submitted.

7. While the data gaps are being filled, currently registered manufacturing-use products containing picloram as the sole active ingredient may be sold, distributed, formulated and used in the United States, subject to the terms and conditions specified in this Standard.

   Rationale: The evidence now before the Agency does not indicate that the continued use of picloram poses significant risks to human health or the environment. Thus, there is no basis, at this time, for a Special Review. With the restricted use classification and precautionary labeling requirements in this Standard, it is the Agency's judgment that continued use of picloram does not cause unreasonable adverse effects on the environment. Although numerous data gaps exist, it is not the policy of the Agency to cancel or withhold registrations solely because of data gaps. (See § 3(c)(2)(B) and 3(c)(7) of FIFRA.) When the data gaps are filled in response to this Standard, the Agency will evaluate whether a change in its regulatory position is necessary.

8. Registrants must provide or agree to develop additional data, as specified in Tables A and B attached to this guidance document, within 90 days after receipt of this document, in order to maintain existing registrations or to permit new registrations of substantially similar picloram MPs. These data must be submitted within the time frames indicated in the data tables.

   Rationale: The Agency requires the data specified in the data tables to complete its evaluation of picloram and to determine if any risk or adverse effects to human health or the environment may result from the use of picloram.

9. The Agency is requiring registrants to place certain precautionary statements on the labels of manufacturing-use and end-use products containing picloram.

   Rationale: Precautionary statements are required on labels as a means of minimizing exposure of the pesticide to humans and to the environment. Since human sensitization studies have shown that a triisopropoanolamine salt combination of 2,4-D and picloram is capable of producing sensitizing reactions, the Agency is requiring a warning of that potential hazard on the label of those formulated products. To prevent residues of picloram from occurring in crops for which tolerances are not established, label warnings prohibiting use of water from ditchbanks for irrigation and prohibiting rotation of non-registered crops are required. Several label precautions are required to avoid the possibility of contaminating aquatic sites (i.e., "Do not discharge effluent...", "Do not apply directly to water..." and "Consult your State Fish and Game Agency...").

10. Reentry intervals are not required.

    Rationale: The Agency has determined, based on the use patterns and available toxicology data, that the criteria in 40 CFR 158.140 for requiring reentry intervals have not been met.

11. The Agency is retaining all labeling that is relevant to spraydrift control. The current labeling advises against aerial application of picloram when wind speeds are 5 to 10 miles per hour. The Agency is also requiring specific spraydrift evaluation studies on a formulation of picloram in order to complete an exposure assessment.

    Rationale: The Agency has received a number of pesticide incident reports with respect to crop and other non-target plant damage and has been involved in administrative hearings concerning picloram have drift to non-target areas. Preliminary drift studies done using picloram showed phytotoxic effects up to 800 feet downwind in winds of 5 to 10 mph. The additional studies will be performed to determine the appropriateness the current label statements: "...Microfoil Boom or equivalent drift control system..." and "Except when applying with a Microfoil Boom a spray thickening agent, such as NALCO-TROL, should be used with this product to aid in reducing spray drift..."

12. The Agency considers the different forms of picloram (acid, salts, esters) to be toxicologically similar so that all of these forms are covered by this single Registration Standard. In most cases, testing on the acid form of picloram fulfills the data requirements for all forms of picloram.

    Rationale: Technical esters and salts of picloram are sold as manufacturing use products and sometimes as formulations. These forms of picloram are considered toxicologically similar to the acid form of picloram so that, in general, testing on the acid form represents testing on the other forms. For certain tests, however, the acid form is not suitable due to its physical properties and one of the other forms must be tested. These exceptions are noted in the data requirements tables. In addition, the Agency's registration guidelines require acute toxicity testing on each of the acids, salts and esters of picloram for labeling purposes.

13. The Agency has established upper limits of 1 ppm for the presence of nitrosamines in the technical product.

    Rationale: Nitrosamine may be a potential contaminant of the various amines used to produce the amine salts of picloram. This chemical is regulated under that rule which requires testing to show that a level of 1 ppm of nitrosamine contamination is not exceeded [45 FR 42854]. These testing requirements are reflected in the data tables at the end of this document.

4. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

To be covered under this Standard, products must contain picloram as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in section 5 of this document.

The application for registration or reregistration of products subject to this Standard must comply with all terms and conditions described in it, including submission of an up-to-date Confidential Statement of Formula, submission of revised labeling, commitment to fill data gaps on a schedule specified by the Agency and, when applicable, offer to pay compensation as required by § 3(c)(1)(D) and § 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. § 136a(c)(1)(D) and § 136a(C)(2)(D). Registration applicants must contact the Agency for specific instructions, including updated information on data requirements and companies whose data must be cited and to whom compensation must be offered.

5. ACCEPTABLE RANGE AND LIMITS

1. Product Composition Standard

To be fully covered under this Guidance Document, manufacturing-use products must contain picloram as the sole active ingredient. Each manufacturing-use product formulation proposed for registration or reregistration must be fully described and an appropriate certification of limits must be included. The label must also state the minimal concentration for the active ingredient. In addition, the active ingredient found in the manufacturing-use picloram products must be substantially similar to that in currently registered technical products. Any manufacturing-use product not meeting these requirements will be considered a new product and will not be registered under this standard.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing picloram, provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products containing picloram may be labeled for formulation into end-use products only for the sites listed below. The attached index entry lists all registered uses, as well as approved maximum application rates and frequencies.

Picloram is applied on Rights-of-way, forest site preparation, pasture and range lands, and small grains. In the control of woody plants picloram is used on alder, aspen, birch, cherry, backgum, sweetgum, locust and many species of maple. Railroads use it for brush control and also for the control of vines such as Virginia creeper, honeysuckle, various morning-glories, and milkweed vine. Both railroads and highway departments use picloram to control perennial weeds such as bouncing bet, wild carrot, thistles, golden rod, milkweed and leafy spurge. In addition to woody plant control, it is an important tool for forest site preparation in the southeastern United States because of its ability to control kudzu and honeysuckle.

On permanent grass pastures in the eastern half of the United States, picloram is used primarily for the control of two woody plant species. These are hawthorn and multiflora rose. On rangeland in the western states, picloram is used to control bitterweed, knapweed, leafy spurge, locoweed, larkspur, mesquite, prickly pear, and snakeweed. In Nebraska, Montana, Wyoming, Minnesota and the Dakotas, it is used to control wild buckwheat and thistles in small grain such as wheat, oats, and barley.

4. Required Labeling

All manufacturing-use picloram products must bear appropriate labeling as specified in 40 CFR 162.10. The guidance package for this standard contains information on label requirements. All labeling changes must appear on all products released for shipment one year from the date the Standard is issued. All labeling changes must appear on all products in channels of trade two years from the issuance date of the Standard.

In addition to the above, the following information must appear on the labeling:

1. Ingredient Statement

   The ingredient statement for MP's must list the active ingredient as:

   Picloram (4-amino-3,5,6-trichloropicolinic acid)

2. Use Pattern Statements

   All manufacturing-use picloram products must state that they are intended for formulation into end-use herbicide products for the aforementioned use patterns. Labeling must specify sites, which are listed in Use Patterns, Section 5.3. No use may be included on the label where the registrant fails to agree to comply with the data requirements in either TABLE A or TABLE B for that use pattern.

3. Precautionary Statements

   Statements for Manufacturing-Use Products

   a. Labels for manufacturing-use picloram products must bear statements reflecting the compound's toxicity. Picloram is in Toxicity Category III by all routes of exposure; the required precautionary statements associated with this category are specified in 40 CFR 162.10.

   b. The following revised environmental hazard statements must appear on all MP's labels:

      "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES* permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency."

* NPDES = National Pollutant Discharge Elimination System

Statements for End-use products

a. The following "restricted use" statement must appear on the label of all picloram products:

"Restricted Use Pesticide"

"Potential for groundwater contamination. Toxic to non-target plants."

"For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification."

"Picloram is a chemical which can travel (seep or leach) through soil and can contaminate ground water which may be used as drinking water. Picloram has been found in ground water as a result of agricultural use. Users are advised not to apply picloram where the soils are very permeable, i.e., well-drained soils such as karst limestone and loamy sands. Your local agricultural agencies can provide further information on the type of soil in your area and the location of ground water."

b. For rotated crops: "Do not rotate food or feed crops on treated land if they are not registered for use with picloram."

c. For ditch bank uses: "Water contaminated with residues of picloram from ditch bank uses shall not be used to irrigate crops which are not registered for use with this chemical."

d. For picloram mixtures with 2,4-D: "WARNING: Avoid contact with skin, eyes or clothing. Avoid repeated skin contact since sensitizing reactions may occur."

e. For non-aquatic uses: "Do not apply directly to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of wastes."

f. For aquatic uses: "Consult your State Fish and Game Agency before applying to public waters. Permits may be required before treating such waters. Do not apply directly to water except as directed on the labeling. Do not contaminate water by cleaning of equipment or disposal of wastes."

4. Tolerance Reassessment

The established tolerances for picloram have been reassessed and found not to be supported by the available data. U.S. tolerances for negligible residues of picloram in or on raw agricultural commodities are as follows (40 CFR 180. 292):

1.0 ppm	Barley, Forage, Green
0.5 ppm	Barley, Grain
1.0 ppm	Barley, Straw
0.2 ppm	Cattle, Fat
5.0 ppm	Cattle, Kidney
0.5 ppm	Cattle, Liver
0.2 ppm	Cattle, MBYP (except kidney and liver)
0.2 ppm	Cattle, Meat
0.05 ppm	Eggs
0.5 ppm	Flax, Seed
0.5 ppm	Flax, Straw
0.2 ppm	Goats, Fat
5.0 ppm	Goats, Kidney
0.5 ppm	Goats, Liver
0.2 ppm	Goats, MBYP (except kidney and liver)
0.2 ppm	Goats, Meat
80.0 ppm	Grasses, Forage
0.2 ppm	Hogs, Fat
5.0 ppm	Hogs, Kidney
0.5 ppm	Hogs, Liver
0.2 ppm	Hogs, MBYP (except kidney and liver)
0.2 ppm	Hogs, Meat
0.2 ppm	Horses, Fat
5.0 ppm	Horses, Kidney
0.5 ppm	Horses, Liver
0.2 ppm	Horses, MBYP (except kidney and liver)
0.2 ppm	Horses, Meat
0.05 ppm	Milk
1.0 ppm	Oats, Forage, Green
0.5 ppm	Oats, Grain
1.0 ppm	Oats, Straw
0.05 ppm	Poultry, Fat
0.05 ppm	Poultry, MBYP (except kidney and liver)
0.05 ppm	Poultry, Meat
0.2 ppm	Sheep, Fat
5.0 ppm	Sheep, Kidney
0.5 ppm	Sheep, Liver
0.2 ppm	Sheep, MBYP (except kidney and liver)
0.2 ppm	Sheep, Meat
1.0 ppm	Wheat, Forage, Green
0.5 ppm	Wheat, Grain
1.0 ppm	Wheat, Straw

There are no CODEX MRL's or Mexican tolerances for picloram. The food uses on barley are acceptable in Canada on a negligible residue basis (0.1 ppm picloram).

EPA's tolerance of 0.5 ppm for residues of picloram in barley grain is higher. Once the additional data being required are received and reviewed, the Agency will determine whether harmonization with the Canadian limit is possible.

It is concluded that the metabolism of picloram in wheat, and in grasses generally, is adequately understood, and the nature of the residue is known. It consists predominantly of picloram, free or conjugated, and of 4-amino-2,3,5-trichloropyridine and 4-amino-3,5-dichloro-6-hydroxy-picolinic acid, free or possibly conjugated. In view of the concern over the two metabolites, they should be included in the tolerance with picloram.

The metabolism of picloram in animals is only partially understood. No metabolites were found in animals, and animals differ from plants in this respect. It is not known if the metabolites were not looked for, were nondetectable, or were not formed in animals. A metabolism study is needed in which ^{14}C-tagged picloram and its metabolites (in proportions simulating the terminal residues in feed items) are fed to a large animal and to the hen, to determine their carryover, in free or conjugated form, to tissues and milk. The need to include these metabolites in tolerances for meat, milk, poultry and eggs, is deferred until the results of such a study are evaluated.

EPA Index to Pesticide Chemicals

PICLORAM

PICLORAM*

TYPE PESTICIDE: Herbicide

FORMULATIONS: Not located.

GENERAL WARNINGS AND LIMITATIONS: There are currently no registered products containing this chemical. +

TIME REQUIRED FOR CONTROL: Not located.

PHYTOTOXICITY TO TARGET WEEDS: Not located.

PHYTOTOXICITY TO CROPS: Not located.

MODE OF ACTION: Not located.

*4-amino-3,5,6-trichloropicolinic acid

FINAL
MAI/MA
h005102

EPA Index to Pesticide Chemicals

PICLORAM, TRIISOPROPANOLAMINE SALT*

TYPE PESTICIDE: Herbicide

FORMULATIONS: EC (0.37 lb/gal)

GENERAL WARNINGS AND LIMITATIONS: An herbicide used to control woody and herbaceous plants in noncrop areas. +

TIME REQUIRED FOR CONTROL: Not located.

PHYTOTOXICITY TO TARGET WEEDS: Not located.

PHYTOTOXICITY TO CROPS: Not located.

MODE OF ACTION: Not located.

WOODY PLANTS CONTROLLED:

ash	@PDMACA
aspen	@PEOABA
locust	@PCQBQA
maple	@PACABA
oak	@PBWAFA
pine	@PDUAHA
rose	@PELASA

*4-amino-3,5,6-trichloropicolinic acid, triisopropanolamine salt.

Issued: 1-30-80 I-005102-1

Site, Dosage and Formulation	Tolerance, Use, Limitations	
RIGHTS-OF-WAY		-
Utility Rights-of-Way	N.F.	/6700600
—	TX state label Registration Number 011465-10170 Formulated with silvex, isooctyl ester plus 2,4-dichlorophenoxyacetic acid, triisopropanolamine salt.	F
COMMERCIAL AND INDUSTRIAL PREMISES		-
Noncrop Areas	N.F.	/6700000
—	TX state label Registration Number 011465-10170 Formulated with silvex, isooctyl ester plus 2,4-dichlorophenoxyacetic acid, triisopropanolamine salt.	F
FOREST, CHAPARRAL, NONAGRICULTURAL AND WASTELANDS		-
Noncrop Areas	N.F.	/6700000
—	TX state label Registration Number 011465-10170 Formulated with silvex, isooctyl ester plus 2,4-dichlorophenoxyacetic acid, triisopropanolamine salt.	F

PICLORAM, TRIISOPROPANOLAMINE SALT

Listing of Registered Pesticide Products by Formulation

0.37 lb/gal emulsifiable concentrate &100.371

picloram, triisopropanolamine salt (005102), 2,4-dichlorophenoxyacetic acid, triisopropanolamine salt (030035) plus silvex, isooctyl ester (082565) #

011465-10170

FINAL
SAI/SAI
005104

EPA Index to Pesticide Chemicals
PICLORAM, POTASSIUM SALT*

TYPE PESTICIDE: Herbicide
FORMULATIONS: FI (34.7%), P/T (11.6%, 5.8%, 2.3%), SC/L (2 lb/gal)

GENERAL INFORMATION: Restricted Use Pesticide. A brush and broadleaf weed control herbicide that can remain active in the soil for more than one season. It is highly mobile in the soil and can be transported laterally in subsurface water. Dosages for this chemical were calculated using the acid equivalent (a.e.).

TIME REQUIRED FOR CONTROL: Not located.

PHYTOTOXICITY TO TARGET WEEDS: Leaf shape is altered at low dosage; tips of new leaves may be narrow; puckering of young leaves may occur; bending or splitting of stem may occur.

MODE OF ACTION: Alters nucleic acid and protein synthesis; a variety of enzymes may be affected.

LIVESTOCK TOLERANCES:

0.5 ppm in liver of cattle, goats, hogs, horses, and sheep; 5 ppm in kidney of cattle, goats, hogs, horses, and sheep; 0.2 ppm in meat, fat and meat byproducts (other than kidney and liver) of cattle, goats, hogs, horses, and sheep; 0.05 ppm in milk, eggs, and in the meat, fat and meat byproducts of poultry.

BROADLEAF WEEDS CONTROLLED:

Canada thistle	(b)	PBFAWBB
dalmation toadflax	(a)	PEUAIBB
dock	(a)	PEAAHAA
field bindweed	(b)	PBGACBB
larkspur	(a)	PEHAFAA
leafy spurge	(b)	PBVAGBE
milkweed	(b)	PAMAAAB
perennial sowthistle	(a)	PBFDCBA
pigweed	(a)	PAAAABI
plumeless thistle	(a)	PBFAQBA
povertyweed	(a)	PBFCCBA
pricklypear	(b)	PASACAA
Russian knapweed	(b)	PBFARBI
silverleaf nightshade	(b)	PEWAIBD
skeletonleaf bursage	(b)	PBFBMBC
sowthistle	(b)	PBFDCAA
sunflower	(a)	PBFBUAA
tansy	(a)	PBFDGBA
toadflax	(b)	PEUAIAA

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* 4-amino-3,5,6-trichloropicolinic acid, potassium salt

WOODY PLANTS CONTROLLED:

aspen	(f)	PEOABAA
brambles	(f)	PELATAA
conifers	(f)	PAAAAAK
grape	(f)	PFKAEAA
hawthorn	(e)	PELAIAA
huisache	(b)	PCQACBE
juniper	(e)	PDUADAA
kudzu	(e)	PCQBPBA
locust	(f)	PCQBQAA
maple	(f)	PACABAA
multiflora rose	(d)	PELASBK
rose	(f)	PELASAA
sumac	(e)	PAHABAA
whitebrush	(c)	PFIABAA

Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations	
AGRICULTURAL CROPS		
Grass pastures Grass rangelands	80 ppm (forage grasses) For rates in excess of 3 lb a.e./A: Do not graze dairy animals in treated areas or cut grass for hay for 16 weeks after treatment; and remove meat animals for three days prior to slaughter when grazing treated area within 16 weeks after treatment. Limit coverage to no greater than 25% of an applicator's acreage, found in any particular watershed. Do not use where a sandy porous surface and substrate overlie ground water 10 feet or less below the surface. Where watersheds have significant slope and where rapid runoff can occur, use spot treatments only.	22013AA 22032AA
1-4 (5.8-11.6% P/T)	Use limited to AL, AR, CO, GA, KS, KY, LA, MO, MS, NC, NM, OK, SC, TN, TX, VA, WV. Broadcast or spot treatment. Apply to individual noxious plants, to clumps, and to larger dense infestations where grasses are already suppressed. Apply anytime soil is not frozen. Do not retreat areas by broadcast application for at least three years. Applications, especially at higher rates, may injure or suppress certain desirable grasses such as smooth bromegrass western wheatgrass, and switchgrass; do not apply where possible injury to such grasses cannot be tolerated. Grass seedlings may be suppressed or killed for up to 2 years after application. Reseeding during this period is not recommended.	
AGRICULTURAL PREMISES		
Around farm buildings, fencerows, storage areas, etc.	NF	66000AA
1-3 (2.3% P/T) 2-3 (2 lb/gal SC/L)	Broadcast or spot treatment for broadleaf weed control. Apply anytime during the growing season, and preferably when rainfall can be expected soon after application. In areas where little or no summer rainfall occurs, apply in late summer or early fall. Apply the SC/L formulation in 50-100 gallons of water.	

Site, Dosage and Formulation (lb. a.e./A)	Tolerance, Use, Limitations	
AGRICULTURAL PREMISES	(continued)	
6-8 (2.3% P/T)	Broadcast or spot treatment for woody plant control. Apply uniformly to the soil over the root zone anytime during the normal growing season where sufficient moisture is available or carry the herbicide into the soil. Where little or no summer rainfall occurs, apply at bud break in late winter or early spring.	
0.25-2.0 (2 lb/gal SC/L)	For an extended range of broadleaf weed control; and for improved control of rootsuckering woody species such as aspen, locust, sassafras and sumac than could be obtained by using either chemical alone. Use the lower dosage for annual broadleaf weed control, the middle of the range for perennial broadleaf weeds and susceptible woody species, and the upper end of the range for hard-to-control woody species. Apply in a total spray volume of 15-25 gallons per acre. Tank mix as an invert emulsion with propylene glycol butyl ether 2,4-dichlorophenoxyacetate; or as a water based spray with butoxypropyl 2,4-dichlorophenoxyacetate.	
RIGHTS-OF-WAY		
Rights-of-way	NF Refer to AGRICULTURAL PREMISES.	67013AA
COMMERCIAL AND INDUSTRIAL PREMISES		
Industrial sites	NF Refer to AGRICULTURAL PREMISES.	67009AA
FOREST, CHAPARRAL, NONAGRICULTURAL ANL WASTELAND		
Forests	NF	30000AA
1-4 (5.8-11.6 P/T)	Broadcast or spot treatment. Apply to individual noxious plants, to clumps, and to larger dense infestations. Apply anytime soil is not frozen.	

Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations	
AQUATIC AREAS		
(adjacent to water)		
Outer ditch banks	NF	65013AA
2-3 (2 lb/gal SC/L)	Broadcast or spot treatment for broadleaf weed control. Apply antime during the growing season, and preferably when rainfall can be expected soon after application. Apply in 50-100 gallons of water.	

Listing of Registered Pesticide Products by Formulation

34.7% (30% a.e.) Formulation intermediate
Picloram, potassium salt (005104)
000464-00502

2.3% (2% a.e.) Pelleted/Tableted
Picloram, potassium salt (005104)
000464-00333

5.8% (5% a.e.) Pelleted/Tableted
Picloram, potassium salt (005104)
000464-00541

11.6% (10% a.e.) Pelleted/Tableted
Picloram, potassium salt (005104)
000464-00320

2 lb/gal Soluble concentrate/Liquid
Picloram, potassium salt (005104)
000464-00323 000464-00421

State Label Registrations:

CA Reg. No.
000464-07099 000464-07103

CO Reg. No.
000464-07098

HI Reg. No.
000464-07097

ID Reg. No.
000464-07096 000464-07102

MN Reg. No.
000464-07095

MT Reg. No.
000464-07094

NB Reg. No.
000464-03383 000464-03385 000464-04528 000464-07093

ND Reg. No.
000464-07092

OR Reg. No.
000464-07091 000464-07101

SD Reg. No.
000464-07090

State Label Registrations (continued)

UT Reg. No.
000464-07089

WA Reg. No.
000464-07088

WV Reg. No.
000464-07100

WY Reg. No.
000464-07087

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA sec. 3(c)(2)(B). The tables following this section list the data required for maintaining the registrability of each product.

EPA has determined that additional generic data described in Table A must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA sec. 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data[1] Must be Submitted. You may determine which generic data you must submit by consulting Table A at the end of this chapter. That table lists the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required studies must be conducted in accordance with EPA approved protocols (such as those contained in the Pesticide Assessment Guidelines [2] or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you do not wish to develop data in support of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

For certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: "Typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter III of this document.

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[1] Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient, regardless of the product's unique composition or specific use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

[2] The Pesticide Assessment Guidelines are available in hard copy or microfiche from the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22161.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-3] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

(b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Pesticide Assessment Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

OR

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

OR

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-4)*/

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*/ FIFRA sec. 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

(Footnote continued on next page)

OR

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

OR

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants subject to a data requirement or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it should encourage joint testing rather than duplicative testing, and that suspension should be withheld in certain cases. to further this goal. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]: and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration.

TABLE A
GENERIC DATA REQUIREMENTS FOR PICLORAM

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	TGAI	Yes	00096376	No
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	Yes	00096376	No
61-3 - Discussion of Formation of Impurities	TGAI	Yes	00096376	No
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis of Product Samples	TGAI	No		Yes
62-2 - Certification of Ingredient Limits	TGAI	No		Yes 4/
62-3 - Analytical Methods to Verify Certified Limits	TGAI	Partially	00036172	Yes
Physical and Chemical Characteristics:				
63-2 - Color	TGAI	Yes	00036149	No
63-3 - Physical State	TGAI	Yes	00036149	No
63-4 - Odor	TGAI	Yes	00036149	No
63-5 - Melting Point	TGAI	Yes	00036149	No
63-6 - Boiling Point	TGAI	N/A 3/		
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	00036149	No

TABLE A
GENERIC DATA REQUIREMENTS FOR PICLORAM

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.120 Product Chemistry (continued)				
63-8 - Solubility	TGAI or PAI	Yes	00036149	No
63-9 - Vapor Pressure	PAI	Yes	00036149	No
63-10 - Dissociation Constant	PAI	Yes	00036149	No
63-11 - Octanol/Water Partition Coefficient	PAI	Yes	00036149	No
63-12 - pH	TGAI	Yes	00036149	No
63-13 - Stability	TGAI	Yes	00036149	No
Other Requirements:				
64-1 - Submittal of samples	N/A[3]	—	—	—

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[1] Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient.

[2] Data must be submitted no later than 6 months from the receipt date of this Standard.

[3] NA = Not applicable for purposes of this Standard.

[4] Upper and lower limits must be provided (and certified) for the active ingredient and each impurity present at $\geq$ 0.1% w/w in the technical product. Certified upper limits for the presence of hexachlorobenzene (HCB) must not exceed 200 ppm. Certified upper limits for the presence of nitrosoamines must not exceed 1 ppm.

TABLE A
GENERIC DATA REQUIREMENTS FOR PICLORAM

Data Requirement	Composition[1]/	Use[2]/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]/
§ 158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B,D,G	Partially	GS0096-001	Yes[4]/
Photodegradation				00059425 00111415 00111515	
161-2 - In water	TGAI or PAIRA	A,B,D,G	Partially		Yes[5]/
161-3 - On soil	TGAI or PAIRA	A,G	No		Yes
161-4 - In Air	TGAI or PAIRA	A	N/A		No[6]/
METABOLISM STUDIES-LAB:				00128976 00111504 00111441	
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,G	Partially		Yes[4]/
162-2 - Anaerobic Soil	TGAI or PAIRA	A	Yes	00128976	No
162-3 - Anaerobic Aquatic	TGAI or PAIRA	D	No		Yes
162-4 - Aerobic Aquatic	TGAI or PAIRA	D	No		Yes
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,D,G	Partially	00044009 00111473 00044017 00111422 00096247 00111516 00128977	Yes[7]/
163-2 - Volatility (Lab)	TEP	A	N/A		No[8]/
163-3 - Volatility (Field)	TEP	A	N/A		No[8]/

TABLE A
GENERIC DATA REQUIREMENTS FOR PICLORAM

Data Requirement	Composition[1]	Use[2] Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§ 158.130 Environmental Fate (continued)					
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A,B	Partially	00044004 00111494 00128977 00044014 00111515 00128981 00044018 00111526 00128987 00044023 00111533 GS0096-002 00059416 00128957 GS0096-003 00111436 00128958 GS0096-004 00111493 00128963	Yes[9]
164-2 - Aquatic (Sediment)	TEP	D	Partially	00111475	Yes[10]
164-3 - Forestry	TEP	G	Partially	00111491 GS0096-003 00128956 GS0096-004 00140317	Yes[11]
164-4 - Combination and Tank Mixes	TEP	A	N/A		No[12]
164-5 - Soil, Long-term	TEP	A	Yes	00044023 00111515	No
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes[13]
165-2 - Rotational Crops (Field)	TEP	A	No		Yes[13]
163-3 - Irrigated Crops	TEP	D	No		Yes[14]
163-4 - In Fish	TGAI or PAIRA	A,B,D,G	Yes	00128947 00128948	
163-3 - In Aquatic Nontarget Organisms	TEP	G	No		No[15]
Subpart K Reentry					No[16]
Ground Water Monitoring			No		Yes[17]

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood, C = Aquatic, Food Crop; D = Aquatic, Nonfood, E = Greenhouse, Food Crop; F = Greenhouse, Nonfood, G = Forestry, H = Domestic Outdoor; I = Indoor.

3/ (a) Data for Hydrolysis 161-1, Photodegradation 161-2/3, and Leaching and Adsorption/Desorption 163-1 must be submitted no later than 6 months from the receipt date of this standard.

(b) Data for Soil Metabolism 162-1 and Field Dissipation 164-1 must be submitted no later than 2 years from the issue date of this Standard.

(c) All other data must be submitted no later than 4 years from the issue date of this Standard.

4/ Additional data are needed for the isooctyl ester of picloram.

5/ Data on the rate of photodegradation at pH 7 are acceptable. Additional rate data are needed for pH 5 and 9. Identification of photoproducts is needed for photolysis at pH 5, 7, and 9. All photodegradation data are needed for the isooctyl ester of picloram.

6/ No data are required because of the relatively low vapor pressure of picloram.

7/ Data for picloram salts are acceptable. All data are required to support the isooctyl ester of picloram.

8/ No data are required because of the relatively low vapor pressure of picloram salts. Data may be needed to support uses of the isooctyl ester of picloram.

9/ Additional data are required to support pellet use for rights-of-way, isoocytl ester use for utility rights-of-way, and pellet use for pasture/range eastern pastures and on rangeland outside of the Southwest.

10/ Additional data are needed to support solution formulation uses in ditchbanks.

11/ Additional data are needed to support both pellet and solution formulations in at least a typical Southeastern forest preparation site.

12/ Data requirements for combination and tank mixes are not necessary for the purposes of this standard.

13/ For crops rotated on treated areas any one of the following will apply:

(a) A tolerance must be obtained for the rotated crop.

(b) The product label must include a restriction against the rotation of crops used for food or feed on treated areas.

(c) Data must be provided to determine time intervals at which crops planted on treated areas will be free of pesticide residues.

14/ In instances where water from treated drainage ditches becomes contaminated with pesticide residues, any one of the following will apply: (a) A tolerance must be obtained for any crop exposed to contaminated water. (b) The product label must include a restriction against the use of water containing picloram residues on crops grown for food or feed. (c) Data must be provided to demonstrate conditions under which water exposed to treated drainage ditches can be used on crops without resulting in illegal plant residues.

15/ Data are not required since laboratory studies indicate that picloram does not accumulate significantly in fish tissue.

16/ No data are required since picloram does not meet the criteria outlined in 40 CFR 158.140 for reentry protection data requirements.

17/ Retrospective Field Study for Picloram

A retrospective field study for picloram is required. In choosing a site for this study the following should be considered:

1) A detailed history of picloram usage on the field should be known, including dates and rates (kg/ha) of application. Application of the granular or pellet formulation is preferable to liquid.

2) The picloram should be applied uniformly over the field site. This criterion would negate applications on electrical utility right-of-way fence-row, etc. Picloram uses which would meet this criterion include pasture-rangeland or forest site preparation. (Applications to wheat also meet this criteria, but most of the rates of application are so low as to negate these uses for consideration.)

3) The soil texture on this field should be coarse so as to enhance leaching. Soil textures meeting this criterion include all sands and loams - those not meeting this criterion include silts and clays.

4) At least two or three wells should be within 1 mile of this field site and down gradient of the ground water flow path. These wells should be shallower than 50 feet, indicating that at least a perched water table exists. If wells are not already present, they can be drilled or driven for the purposes of this study. If this is done, nested wells should be created.

5) Some hydrogeology of the area should be known, particularly the depth to ground water. This information could be obtained from the well builders.

A suggested use pattern which meets these criteria is forest site preparation on the coastal Southeast. Reasons for choosing this use include: 1) picloram use in forest site preparation occurs primarily in the Southeast, 2) the history of use would have to be well known since the picloram is only applied once (the picloram should have been applied within 2 years of the first data collection), 3) soil textures which meet the criterion 4) above are prevalent on the Southeast coast, particularly in Florida, and 5) the intensity of spring and summer storms is conducive to leaching in this part of the country.

Once a field site has been located, the study will be designed. A preliminary set of considerations includes:

1) The soil should be well characterized in terms of percent sand, silt, and clay fractions, percent organic matter, pH, water-holding capability. This characterization should extend from the surface to at least 10 feet deep.

2) Between five and ten soil cores should be taken at one time or within a period of a couple of weeks. These cores will be used to characterize the soil (#1 above) and to describe the spatial distribution of picloram in the field. The pattern of sampling should be well thought out in order to lend statistical significance to the study design. Each soil core should extend at least 10 feet deep, and separate samples at 6-inch to 1-foot increments should be analyzed for total picloram.

3) Well water samples should be taken quarterly (or 4 times/year).

4) Do all this for two similar fields.

TABLE A
GENERIC DATA REQUIREMENTS FOR PICLORAM

Data Requirement	Composition 1/	Use[2]/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]/
§ 158.135 Toxicology					
ACUTE TESTING:	TGAI-Acid	-	No		Yes[4]/
	TIPA Salt	A,B,G	No		Yes
81-1 - Oral	IPA Salt	A,B,G	No		Yes
Rat	Isooctyl ester	A,B,G	Yes	GS0096-005	No
	K+ Salt	A,B,G	No		Yes
	K+ Salt	A,B,G	No		Yes
81-2 - Dermal	TGAI-Acid	-	No		Yes[4]/
Rabbit	TIPA salt	A,B,G	No		Yes
	IPA salt	A,B,G	No		Yes
	Isooctyl ester	A,B,G	Yes	GS0096-005	No
81-3 Inhalation	TGAI-Acid	-	No		No
Rat	TIPA Salt	A,B,G	No		Yes
	IPA Salt	A,B,G	No		Yes
	Isooctyl ester	A,B,G	No		Yes
	K+ Salt	A,B,G	No		Yes
81-6 - Sensitization	2,4-D Picloram	A,B,G	Yes	00041114	No
	TIPA salt			00041115	No
	Tordon 22K	A,B,G	Yes	00128765	No
				GS0096-006	

TABLE A
GENERIC DATA REQUIREMENTS FOR PICLORAM

Data Requirement	Composition[1]	Use[2] Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§ 158.135 Toxicology (continued)					
CHRONIC TESTING:					
83-1 - Chronic Toxicity					
2 species: Rodent	TGAI-Acid	A,B,G	No		Yes[5]
Nonrodent	TGAI-Acid	A,B,G	No		Yes[5]
83-2 - Oncogenicity Study					
2 species: Rat	TGAI-Acid	A,B,G	Partially	00081275	Yes[5]
Mouse	TGAI-Acid	A,B,G	Yes	00081275	No
83-3 - Teratogenicity					
2 species: Rat	TGAI-Acid	A,B,G	Yes	00030284	No
Rabbit	TGAI-Acid	A,B,G	No		Yes[6]
83-4 - Reproduction, 2-generation	TGAI-Acid	A,B,G	Yes	00041098	No
MUTAGENICITY TESTING:					
84-2 - Gene Mutation	TGAI	A,B,H,I	Partially	00123282	Yes[6][7]
84-2 - Chromosomal Aberration	TGAI	A,B,H,I	No		Yes[6][7]
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,B,H,I	No		Yes[6][7]

TABLE A
GENERIC DATA REQUIREMENTS FOR PICLORAM

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§ 158.135 Toxicology (continued)					
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding -	TGAI-Acid	A,B,G	Yes	00041093 00069969 00098317 00110537	No
Rodent	TIPA	A,B,G	Yes	00041094	No
non-rodent	TGAI-Acid	A,B,G	Yes	00115034	No
82-2 - 21-Day Dermal	TGAI-Acid	A,B,G	No	-	No
82-3 - 90-Day Dermal	TGAI-Acid	A,B,G	No	-	No
82-4 - 90-Day Inhalation	TGAI-Acid	A,B,G	No	-	No
82-5 - 90-Day Neurotoxicity	TGAI-Acid	A,B,G	No		No
SPECIAL TESTING:					
85-1 - General Metabolism	PAI or PAIRA of Acid, K-Salt, NH_4 Salt	A,B,G	Partially	00098321 00011409	Yes 4/
85-2 - Domestic Animal Safety	Choice	A,B,G	Yes	00128765 GS0096-006	No No

GENERIC DATA REQUIREMENTS FOR PICLORAM

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product. PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabeled, Choice = Choice of several test substances determined on a case-by-case basis; TIPA = Triisopropanolamine salt; IPA = Isopropylamine.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood, C = Aquatic, Food Crop; D = Aquatic, Nonfood, E = Greenhouse, Food Crop, F = Greenhouse, Nonfood, G = Forestry, H = Domestic Outdoor, I = Indoor.

3/ Data must be submitted no later than 1 year from the receipt of this Standard.

4/ If the picloram is an in-house intermediate, further acute testing of the technical is not warranted.

5/ Data must be submitted no later than 3 years from the receipt of this Standard.

6/ Data must be submitted no later than 1 year from the receipt of this Standard.

7/ See data requirement and guidelines for appropriate mammalian in vitro test to cover area of genetic toxicity.

TABLE A
GENERIC DATA REQUIREMENTS FOR PICLORAM

Data Requirements	Composition[1]/	Use Pattern[2]/	Does EPA Have Data To Satisfy This Requirement? (Yes No or partically)	Bibliographic Citation	Must Additional[3]/ Data be Submitted Under FIFRA Section 3(c)(2)(B)?
§150.142 Spray Drift					
201-1 - Droplet Size Spectrum	TEP	B,G	No		Yes
202-1 - Drift Field Evaluation	TEP	B,G	No		Yes

1/ Composition: TEP = Typical end-use product.
2/ Use Pattern: B = Terrestrial, Nonfood Crop; G = Forestry.
3/ Data must be submitted no later than 1 year from receipt of this Standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR PICOLORAM

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation		Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? [3]
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING:						
71-1 - Avian Oral LD_{50}	TGAI(acid) (and potassium salt)	A,B,	No			Yes
71-2 - Avian Dietary LC_{50}	TGAI (acid)	A,B	Yes		00022923	No
	TGAI(potassium salt, isooctyl ester)		No			Yes [3]
71-3 - Wild Mammal Toxicity			No			No
71-4 - Avian Reproduction			No			No
71-5 - Simulated and Actual Field Testing - Mammals and Birds		A,B	N/A			No
AQUATIC ORGANISM TESTING:						
70-1 - Special Test (monitoring)	TEP	B	No			Yes [4]
72-1 - Freshwater Fish LC_{50}	TGAI(acid) (salt, isooctyl ester)	A,B	Yes	GS0144-012 00112016 00129076	00129078 GS0096-007	No [5]
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI(acid)	A,B	Yes	GS0144-012 00129076 GS0096-008		No [6]
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	B	Partially	00111560 00129073		No

TABLE A
GENERIC DATA REQUIREMENTS FOR PICLORAM

Data Requirement	Composition 1/	Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
AVIAN AND MAMMALIAN TESTING:					
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI(acid) (salt, isooctyl ester)	A,B	No		Reserved 7/
72-5 - Fish Life-Cycle	TGAI(acid) (salt, isooctyl ester)	A,B	No		Reserved 7/
72-6 - Aquatic Organism Accumulation			No		No
72-7 - Simulated or Actual Field Testing - Aquatic Organisms			No		Reserved 7/

1/ Composition: TGAI = Technical Grade of the active ingredient; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Crop; C = Aquatic, Food Crop; D = Aquatic Nonfood; E = Greenhouse, Nonfood; G = Forestry; H = Domestic outdor; I = Indoor.

3/ Use bobwhite quail (waive mallard duck species at this time).

4/ Data must be submitted 6 months from the receipt of this Standard. Support use on forestry, ditch banks, rangelands,(potassium salt liquid and pellet). Pending these results, residue monitoring may be required on the isooctyl ester, at a later date.

5/ Waive the requirements for other acute fish studies because of similarity in toxicity values noted in previously submitted studies (acid, salt, isooctyl ester).

6/ Waive requirements for other aquatic invertebrate studies on salt and isooctyl ester. This is based on the acute toxicity values from other aquatic studies that showed slight toxicity.

7/ These tests may be required pending the ????

TABLE A
GENERIC DATA REQUIREMENTS FOR PICLORAM

Data Requirements	Composition [1/]	Use Pattern [2/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? [3/]
§158.150 Plant Protection					
121-1 - **TARGET AREA PHYTOTOXICITY:**	EP	B	No		No [4/]
NONTARGET AREA PHYTOTOXICITY:					
TIER I					
122-1 - Seed Germination/ Seedling Emergence	TGAI	B	No		Yes
122-1 - Vegetative Vigor	TGAI	B	No		Yes
122-2 - Aquatic Plant Growth	TGAI	B	No		Yes
TIER II					
123-1 - Seed Germination/ Seedling Emergence	TGAI	B	Reserved [5/]		
123-1 - Vegetative Vigor	TGAI	B	Reserved [5/]		
123-2 - Aquatic Plant Growth	TGAI	B	Reserved [5/]		
TIER III					
124-1 - Terrestrial Field	TEP	B	Reserved [6/]		
124-2 Aquatic Field	TEP	B	Reserved [6/]		No [4/]

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product. EP = End-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood Crop; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry;
H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted no later than 6 months from receipt of the Standard.

4/ These requirements are generally waived unless EPA determines that there is a phytotoxicity problem.

5/ Reserved pending evaluation of Tier I results.

TABLE A
GENERIC DATA REQUIREMENTS FOR PICLORAM

Data Requirement	Composition[1]	Use[2] Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honeybee acute contact	TGAI, Potassium salt, Isooctyl ester	A,B,G	Yes	00036935	No
141-2 - Honeybee - toxicity of residues on foliage	TEP	A,B,G	No		No[4]
141-4 - Honeybee subacute feeding study	TGAI, Potassium salt, Isooctyl ester		Reserved[5]		
141-5 - Field testing for pollinators	TEP	A,B,G	No		No[4]
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	TGAI, Potassium salt Isooctyl ester		Reserved[6]		
142-2 - Aquatic insect life-cycle study	TGAI, Potassium salt Isooctyl ester		Reserved[6]		
142-3 - Simulated or actual field testing for aquatic insects	TGAI, Potassium salt Isooctyl ester		Reserved[6]		
143-1 thru 143-3 - NONTARGET INSECT TESTING-PREDATORS AND PARASITES:	TGAI, Potassium salt Isooctyl ester		Reserved[6]		

TABLE A
GENERIC DATA REQUIREMENTS FOR PICLORAM

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood, G = Forestry; H = Domestic Outdoor; I = Indoor.
3/ Data must be submitted no later than 6 months from receipt of this Standard.
4/ As data from the acute test indicate low toxicity to bees, no further testing is required.
5/ Reserved pending development of test methodology.
6/ Reserved pending Agency decision as to whether the data requirement should be established.

TABLE A
GENERIC DATA REQUIREMENTS FOR PICLORAM

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Yes	00011527 00041136 00059411 00037880	No
- Livestock	PAIRA	Partially	00023105 00041125 00041126 00041123	Yes 2/*
171-4 - Residue Analytical Method				
- Plant residues	TGAI & Metabolites	Partially	00026751 00045363 00026752 00045366 00027288 00045409 00026750	Yes 3/*
- Animal residues	TGAI & Metabolites	Partially	00069973 00073974 00073972 00078483	Yes 3/*
171-4 - Storage Stability Data	PAIRA	No		Yes 4/*

1/ Composition: TGAI = technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product; EP = End-use product.

2/ A metabolism study is needed in which 14_C ring labeled picloram and its metabolites (in proportions simulating the terminal 14_C residues in feed items) are fed to a ruminant and to the hen, to determine their carryover, in free or conjugated form to tissues, milk, and eggs.

3/ New methodology may be needed to determine the previously undetermined entities (metabolites, free or conjugated) in plant and animal tissues (assuming these are shown to be present in animals by the required metabolism studies).

4/ Data on the storage stability of residues of picloram and its metabolites free or conjugated in plant and animal samples are required.

*/ Data must be submitted no later than 1 year from receipt of this Standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR PICLORAM

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue - Residue studies for each food use				
- Grain Crops of Wheat, Barely, Oats	TEP	Partially	00128714 00036186 00036171 00036170	Yes 2/ 3/ 4/*
- Processed Foods Milled Fractions	TEP	Partially	00045369	Yes 2/ 3/ 4/*
- Forage and Straw of Barley, Oats, Wheat	TEP	Partially	00128714 00036186 00036171 00036170	Yes 2/ 3/ 4/*
- Flaxseed and Straw		Partially	00085060 00026753	Yes 2/ 3/ 6/*
- Forage Grasses	TEP	Partially	00128714 00111470 0011527	Yes 2/ 3/ 4/ 5/*

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product.

2/ If metabolites in the plant and animal tissues are not determined by current methodology, new data may be needed on on residues of picloram and its metabolites, free or conjugate, in cropland and animal tissue.

3/ Data are needed on storage stability.

4/ Data are needed to reflect ground and aerial application.

5/ Better geographical representation in major growing areas is needed.

6/ If new data show that residues in fact are present in flaxseed new data for residues in hulls and meal will be needed.

*/ Data must be submitted no later than 1 year from receipt of this Standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR PICLORAM

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.125 Residue Chemistry (continued)				
Residue studies in food-producing animals				
- Meat	TGAI	Partially	00073973 00045374 00045376	Yes 2/ 3/*
- Milk	TGAI	Partially	00045372 00073921	Yes 2/ 3/*
- Poultry	TGAI	Partially	00035959	Yes 2/ 3/*
- Eggs	TGAI	Partially	00035959	Yes 2/ 3/*

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product; EP = End-use product.

2/ If metabolites in the plant and animal tissues are not determined by current methodology, new data may be needed on residues of picloram and its metabolites, free or conjugate, in cropland and animal tissue.

3/ Data are needed on storage stability.

*/ Data must be submitted no later than 1 year from the receipt of this Standard.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS OF PICLORAM

Data Requirement	Composition [1]		Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? [2]
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Acute Oral Toxicity - Rat	MP	IPA	No		Yes
		K+, TIPA	No		Yes
		Acid	No		Yes
		IOE	Yes	00128765	No
81-2 - Acute Dermal Toxicity - Rabbit	MP	Acid, K+	No		Yes
		TIPA	No		Yes
		IPA	No		Yes
		IOE	No		Yes
81-3 - Acute Inhalation Toxicity - Rat	MP	Acid	No		Yes
		K+	No		Yes
		TIPA	No		Yes
		IPA	No		Yes
		IOE	No		Yes
81-4 - Primary Eye Irritation - Rabbit	MP	Acid	No		Yes
		K+	No		Yes
		TIPA	No		Yes
		IPA	No		Yes
		IOE	No		Yes
81-5 - Primary Dermal Irritation - Rabbit	MP	Acid	No		Yes
		K+	No		Yes
		TIPA	No		Yes
		IPA	No		Yes
		IOE	No		Yes
81-6 - Dermal Sensitization - Guinea Pig	MP	Acid	No		Yes
		K+	Yes	00128765	No
		TIPA	No		Yes
		IPA	No		Yes
		IOE	No		Yes

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS OF PICLORAM

1/ Acid = Picloram Acid; TIPA = Triisopropylamine Salt of Picloram; IPA = Isopropylamine salt of picloram; K+ = Potassium salt of picloram; IOE = Isooctyl ester of picloram.

2/ Data must be submitted 6 months after receipt of this Standard.

NOTE: These testing requirements may be satisfied by table A if they are the same as the Technicals.

TABLE B
PRODUCT SPECIFIC MUP REQUIREMENTS

Data Requirement	Composition[1]	Use[2] Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
Physical and Chemical Characteristics:					
63-2 - Color	MUP		Yes	00036149	No
63-3 - Physical State	MUP		Yes	00036149	No
63-4 - Odor	MUP		Yes	00036149	No
63-7 - Density, Bulk Density, or Specific Gravity	MUP		No		Yes
63-12 - pH	MUP		Yes	00036149	No
63-14 - Oxidizing/Reducing Action	MUP		No		Yes
63-15 - Flammability	MUP (for combustible liquids only)		No		Yes
63-16 - Explodability	MUP		No		Yes
63-17 - Storage Stability	MUP		Yes	00036149	No
63-18 - Viscosity	MUP (for liquid Products)		No		Yes
63-19 - Miscibility	MUP (for emulsifiable liquid products)		No[4]		Yes[4]
63-20 - Corrosion	MUP		Yes		No

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TABLE B
PRODUCT SPECIFIC MUP REQUIREMENTS

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional[2]/ Data be Submitted Under FIFRA Section 3(c)(2)(b)?
158.120 Product Chemistry				
Product Identity:				
61-1 - Product Identity & Disclosure of Ingredients	MUP	Yes	00096376	No
61-2 - Description of Beginning Materials and Manufacturing Process	MUP	Yes	00096376	No
61-3 - Discussion of Formation of Impurities	MUP	Yes	00096376	No
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis	MUP	No		Yes
62-2 - Certification of Limits	MUP	No		Yes
62-3 - Analytical Methods for Enforcement of Limits	MUP	Partially	00096376	Yes

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1/ Table reflects the status of data requirements for the MUP of Picloram which is equivalent to the table A. All of the requirements of this table would apply to a new MUP.

2/ Data must be submitted no later than 6 months from the receipt of this Standard.

3/ Data must be submitted no later than 6 months from the receipt of this Standard.

4/ These data requirements are not applicable.

The extension request should state the reasons why you believe that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: Unless stated otherwise in Section I, Regulatory Position and Rationale, this Section applies only to manufacturing use products, not to end use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA sec. 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

Table B--Product-Specific Data Requirements for Manufacturing Use Products--lists the product specific data you must submit. Data that are required to be submitted are identified in the column of those tables entitled "Must Data By Submitted Under §3(c)(2)(B)."

IV. SUBMISSION OF REVISED LABELING

Note: This section applies to end use products only to the extent described in Section I (Regulatory Position and Rationale). Otherwise, the following information pertains exclusively to manufacturing use products.

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients. Labeling requirements are set out in 40 CFR 162.10 (see Appendix IV-1) and are summarized for products containing this active ingredient as part of this Guidance Document (See Appendix IV-2). Applications submitted in response to this notice must include draft labeling for Agency review.

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*/ Product specific data pertain to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicity data.

If you fail to submit revised labeling information complying with this section (supplemented by requirements described in Section I, Regulatory Position and Rationale), EPA may issue a notice of intent to cancel the registration under FIFRA sec. 6(b)(1).

A. Label Contents

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Appendix IV-2.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR 162.10(f)]

Item 6. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. See Appendix IV-1. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR 162.10 (h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR 162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C).

c. A "non-flammable aerosol" is one which meets the following criteria:

i. The flame extension is zero inches;

ii. There is no flashback; and

iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "non-flammable (gas, liquid, etc.)" on the label. It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section I indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

A. Classification Labeling Requirements

If Section I of this Guidance Document indicates that your product has been classified for restricted use, the following label requirements apply:

1. Front panel statement of restricted use classification.

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

   b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

   a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

   b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

   c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

B. Compliance Schedules

No product with a use classified for restricted use under this Standard may be released for shipment by the registrant or producer after one year from the date of issuance of this Standard, unless such product bears the restricted use classification. All products still in channels of trade after two years from the date of issuance of this Standard must be labeled for restricted use.

Item 9B. [There is no Item 9B].

Item 9C. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. [There is no Item 10B].

Item 10C. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-4 to determine the disposal instructions appropriate for your products.

Item 10D. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR 162.10]

B. Collateral Labeling

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Robert J. Taylor
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Phone No. (703)557-1800

A. For Manufacturing Products (MP) containing (name of pesticide) as an active ingredient.

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

2. Within 6 months from receipt of this document you must submit:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

c. Two copies of any required product-specific data.

d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. The labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to PR Notice 84-4 (enclosed) for latest requirements.

3. Within the times set forth in Table A, all generic data must be submitted.

Note: If for any reason any required test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager.

B. For Manufacturing Use Products containing (name of pesticide) in combination with other active ingredients

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

2. Within the times set forth in Table A, all generic data must be submitted.

Note: If for any reason any required test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager.

C. For End Use Products containing (name of pesticide) alone or in combination with other active ingredients:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

2. Within 6 months from receipt of this document you must submit:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product-Specific Data Report, EPA Form 8580-4 (Appendix III-1).

c. Two copies of any required product-specific data. (Refer to Table C).

d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. Labeling should be either typewritten text on 8 1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8 1/2 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to PR Notice 84-4 (enclosed) for latest requirements.

3. For those end use product registration that are not eligible for the formulator's exemption, submit all generic data within the time set forth in Table A.

D. For intrastate products containing (name of pesticide) either as the sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

Appendix II-1

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies: see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

    (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

    (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

    (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

    (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A: the second, 123456-B: the 26th, 123456-Z: and the 27th, 123456-AA.

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REGISTRATION STANDARD BIBLIOGRAPHY
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MRID	Citation
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00011527	Peterson, G.W. (1967) Dothistroma needle blight of Austrian and ponderosa pines: Epidemiology and control. Phytopathology 57 (?/Apr):437-441. (Also in unpublished submission received Dec 30, 1970 under 1109-25; submitted by Cities Service Co., Minerals Group, Atlanta, Ga.; CDL:024579-H)
00022923	Hill, E.F.; Heath, R.G.; Spann, J.W.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds: Special Scientific Report--Wildlife No. 191. (U.S. Dept. of the Interior, Fish and Wildlife Service, Patuxent Wildlife Research Center; unpublished report)
00023105	Fisher, D.E.; St. John, L.E., Jr.; Guntenman, W.E.; et al. (1965) Fate of Banvel T, Ioxynil, Tordon and Trifluorilin in the dairy cow. Journal of Dairy Science 48(12):1711-1715. (Also in unpublished submission received Apr 8, 1976 under 876-203; submitted by Velsicol Chemical Corp., Chicago, Ill.; CDL:235226-Y)
00026750	Dow Chemical Company (1966) Determination of Residues of Tordon Acid in Wheat Grain by Gas Chromatography. Method ACR 65.3R dated Feb 4, 1966. (Unpublished study received Nov 21, 1967 under 8F0660; CDL:091151-K)
00026751	Dow Chemical Company (1965) Gas Chromatographic Method for the Determination of Residues of Tordon Acid in Wheat Straw. Method ACR 65.4R dated Nov 15, 1965. (Unpublished study received Nov 21, 1967 under 8F0660; CDL:091151-L)
00026752	Dow Chemical Company (1966) Determination of Residues of Tordon Acid in Wheat Straw by Gas Chromatography. Method ACR 66.5 dated May 6, 1966. (Unpublished study received Nov 21, 1967 under 8F0660; CDL:091151-M)
00026753	Leahy, J.S.; Taylor, T. (1967) A gas-chromatographic determination of residues in Picloram. Analyst 92(?/Jun):371-374. (Also in unpublished submission received Nov 21, 1967 under 8F0660; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:091151-O)
00027288	Dow Chemical Company (1967) Determination of Residues of Tordon Acid in Barley Straw by Gas Chromatography. Method ACR 67.4 dated Jul 7, 1967. (Unpublished study received Nov 21, 1967 under 8F0660; CDL:091151-N)

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MRID	Citation
00030284	Thompson, D.J.; Emerson, J.L.; Strebing, R.J.; et al. (1972) Teratology and postnatal studies on 4-Amino-3,5,6-trichloropicolinic acid (Picloram) in the rat. Food and Cosmetics Toxicology 10 (?):797-803. (Also in unpublished submission received Jan 15, 1980 under 464-323; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:241615-A)
00035959	Riley, V.; Kutschinski, A.H. (1967) Residues of Tordon acid in Eggs and Tissues from Chickens Fed the Herbicide. (Unpublished study received Jul 3, 1975 under 6F1653; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:094501-E)
00036149	Dow Chemical Company (19??) Name, Identity, and Structure of the Pesticide Chemical: [Picloram]. (Unpublished study received Jul 3, 1975 under 6F1653; CDL:094499-A)
00036170	Southwick, L.; Behrens, R.; Hartman, G.P. (1975) A Residue Study of Picloram and 2,4-Dichlorophenoxyacetic acid in Wheat following One, Two and Three Years Use of Picloram and 2,4-D (Tordon(R) 202 Mixture): GHP-913. (Unpublished study received Jul 3, 1975 under 6F1653; prepared in cooperation with Univ. of Minnesota and Univ. of Montana, submitted by Dow Chemical Co., Indianapolis, Ind.; CDL:094498-E)
00036171	Bjerke, E.L.; Dietrich, I.; Baker, L.O.; et al. (1975) A Residue Study of Picloram and 2,4-D in Wheat and Barley following Postemergence Application of Tordon 22K Weed Killer plus Formula 40 Herbicide: GH-C 821. (Unpublished study received Jul 3, 1975 under 6F1653; prepared in cooperation with Univ. of Montana and Montana State Univ., submitted by Dow Chemical Co., Indianapolis, Ind.; CDL:094498-F)
00036172	Dow Chemical Company (1975) Analytical Method: Picloram Technical. Method No. 60180 under May 28, 1975. (Unpublished study received Jul 3, 1975 under 6F1653; CDL:094499-W)
00036186	Allied Chemical Corporation (1959) Urab: Weed Killers: 1959 Agricultural Development Bulletin. (Unpublished study received Jul 23, 1959 under 218-446; CDL:001098-A)
00036935	Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1975) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. By University of California, Dept. of Entomology. ?: UC, Cooperative Extension. (Leaflet 2287; published study.)

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00041093	Dow Chemical Company (1962) Results of 90-Day Dietary Feeding Studies of 4-Amino-3,5,6-trichloropicolinic acid in Rats. (Unpublished study received Nov 6, 1967 under 0F0863; CDL:094525-C)
00041094	Dow Chemical Company (1964) Results of 90-Day Dietary Feeding Studies of Triisopropanolamine salt of 4-Amino-3,5,6-trichloropicolinic acid in Rats. (Unpublished study received Nov 6, 1967 under 0F0863; prepared in cooperation with International Research and Development Corp; CDL:094525-D)
00041098	McCollister, D.D.; Copeland, J.R.; Oyen, F. (1967) Results of Fertility and Reproduction Studies in Rats Maintained on Diets Containing Tordon(R) Herbicide. (Unpublished study received Nov 6, 1967 under 0F0863; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:094525-H)
00041114	Dow Chemical Company (1964?) Skin Contact Studies with Humans. Summary of studies 094525-Z through 094525-AC. (Unpublished study received Nov 6, 1967 under 0F0863; CDL:094525-Y)
00041115	Hill Top Research Institute, Incorporated (1963) Repeated Insult Patch Test of M-2431 and Three Other Unrelated Materials. (Unpublished study received Nov 6, 1967 under 0F0863; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:094525-Z)
00041123	Dow Chemical Company (1964) The Metabolism of Tordon Herbicide by the Rat. (Unpublished study received Nov 6, 1967 under 0F0863; CDL:094525-AH)
00041125	Dow Chemical Company (1964) A Residue Study on Tissues from Beef Cattle Fed Diets Containing Tordon Herbicide. (Unpublished study received Nov 6, 1967 under 0F0863; CDL:094525-AJ)
00041126	Leasure, J.K.; Getzendaner, M.E. (1965) The Determination of Residues of Tordon in Various Tissues from Rabbits. (Unpublished study received Nov 6, 1967 under 0F0863; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:094525-AK)

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00044009	Farmer, W.J.; Aochi, Y. (1974) Picloram sorption by soils. Soil Science Society of America Proceedings 38:418-423. (Also in unpublished submission received May 5, 1975 under 464-323; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:221997-J)
00044014	Goring, C.A.I.; Youngson, C.R.; Hamaker, J.W. (1966) Residues of Tordon in Soil from Field Experiments Treated with Tordon and Sampled at Various Intervals after Treatment. Includes undated method entitled: Bioassay method for the determination of residues of Tordon herbicide in soil. (Unpublished study received May 5, 1975 under 464-323; submitted by Dow Chemical U.S.A.; CDL:221997-O)
00044017	Helling, C.S. (1971) Pesticide mobility in soils: II. Applications of soil thin-layer chromatography. Soil Science Society of America Proceedings 35:737-748. (Also in unpublished submission received May 5, 1975 under 464-323; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:221997-S)
00044018	Lutz, J.F.; Byers, G.E.; Sheets, T.J. (1973) The persistence and movement of Picloram and 2,4,5-T in soils. Journal of Environmental Quality 2(4):485-488. (Also in unpublished study received May 5, 1975 under 464-323; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:221997-T)
00044023	Youngson, C.R.; Gantz, G.L.; Gantz, R.L.; et al. (1966) Residues of Tordon in Soil from Fields Treated for Selective Weed Control with Tordon(R) Herbicide. Includes undated method entitled: Bioassay method for the determination of residues of Tordon herbicide in soil. (Unpublished study received May 5, 1975 under 464-323; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL: 221997-Z)
00045363	Swann, R.L.; Pettyjohn, M.A.; Bjerke, E.L. (1972) Determination of Residues of Picloram in Wheat, Barley and Oat Green Forage, Grain and Straw by Gas Chromatography. Method ACR 72.7 dated May 12, 1972. (Unpublished study received Jul 3, 1975 under 6F1653; prepared in cooperation with International Research and Development Corp., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:094500-A)

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00045369	Bjerke, E.L.; Ervick, D.K. (1975) A Residue Study of Picloram and 2,4-D in Milled Wheat Fractions: GH-C 798. (Unpublished study received Jul 3, 1975 under 6F1653; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:094501-B)
00045372	Kutschinski, A.H.; Stevenson, G.T. (1967) Residues of Tordon acid in Milk from Cows Fed the Herbicide. (Unpublished study including experiment no. 3-1400-5, received Jul 3, 1975 under 6F1653; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:094501-F)
00045374	Kutschinski, A.H.; Riley, V. (1967) Residues of Tordon acid in Tissues from Steers Fed the Herbicide. (Unpublished study received Jul 3, 1975 under 6F1653; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:094501-H)
00045376	Bjerke, E.L.; Riley, V.; Bucek, O.C.; et al. (1969) Residues of Picloram in Sheep Tissues. (Unpublished study received Jul 3, 1975 under 6F1653; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:094501-J)
00045409	Dow Chemical Company (1966) Determination of Residues of Tordon acid in Grass by Gas Chromatography. Analytical method ACR 66.7 dated Jul 11, 1966. (Unpublished study received Aug 4, 1969 under 0F0863; CDL:093160-G)
00059416	Scifres, C.J.; Hahn, R.R.; Diaz-Colon, J.; et al. (1971) Picloram persistence in semiarid rangeland soils and water. Weed Science 19(4):381-384. (Also in unpublished submission received Sep 26, 1974 under 464-323; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:120353-G)
00059425	Youngson, C.R. (1968) Effect of Source and Depth of Water, and Concentration of 4-Amino-3,5,6-trichloropicolinic acid on Rate of Photodecomposition by Sunlight. (Unpublished study received Sep 26, 1974 under 464-323; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:120353-P)
00066969	Food and Drug Research Laboratories, Incorporated (1976) Eye Irritation Test in Rabbits: Laboratory No. 5185a. (Unpublished study received Aug 25, 1978 under 3533-58; submitted by Airkem, Div. of Airwick Industries, Inc., Carlstadt, N.J.; CDL:235636-C)

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MRID	Citation
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00073921	Higham, J.W. (1973) Cycocel(R): Cycocel Residues in Affined Raw Sugar (Ewa and Hilo, Hawaii): Report No. C-370. Includes methods M-369 and M-440. (Unpublished study received Jan 28, 1974 under 4G1461; submitted by American Cyanamid Co., Princeton, N.J.; CDL:093894-R)
00073972	Dow Chemical Company (1967) Residue Determination Method: Determination of Residues of Tordon Acid in Milk by Gas Chromatography. Method ACR 67.3 dated Jun 22, 1967. (Unpublished study received Mar 3, 1970 under 8F0660; CDL:090780-I)
00073974	Dow Chemical Company (1967) Residue Determination Method: Determination of Residues of Tordon Acid in Bovine Tissues by Gas Chromatography. Method ACR 67.2 dated Jun 21, 1967. (Unpublished study received Mar 3, 1970 under 8F0660; CDL:090780-K)
00078483	Dow Chemical Company (1967) Residue Determination Method: Determination of Residues of Tordon(R) Acid in Chicken Eggs and Tissues by Gas Chromatography. Method ACR 67.5 dated Sep 14, 1967. (Unpublished study received on unknown date under 4E1489; submitted by Montana, Dept. of Agriculture, Helena, Mont.; CDL: 093949-B)
00081275	U.S. National Institutes of Health (1978) Bioassay of Picloram for Possible Carcinogenicity. By National Cancer Institute, Carcinogenesis Program. Bethesda, Md.: NIH. (CAS no. 1918-02-1; NCI-CG-TR-23; DHEW publication no. NIH 78-823; published study; CDL:241370-B)
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00096247	Harich, J. (1964) Tentative of Nicon-PQ. (Unpublished study received Dec 23, 1964 under 8052-1; prepared by Harich Chemical Co., submitted by Vetanicon Chemical and Drug, Inc., Stowe, Pa.; CDL:226615-D)
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00110537 Gorzinski, S.; Johnson, K.; Campbell, R.; et al. (1982) Technical Grade Picloram: Results of a 13-week Dietary Toxicity Study in Fischer 344 Rats: Laboratory Report Code HET K-038323-(32). Final rept. (Unpublished study received Aug 23, 1982 under 464-502; submitted by Dow Chemical U.S.A., Midland, MI; CDL: 248162-D)

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Appendix II-3

OMB Approval No. 2000-0468

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	**GUIDANCE DOCUMENT DATE** **ACTIVE INGREDIENT**
NAME OF FIRM	**EPA COMPANY NUMBER**

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	**DATE OF OFFER**

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	**SIGNATURE**	**DATE**

PRODUCT SPECIFIC DATA REPORT

EPA Registration No.________________ Guidance Document for________________________

Date________________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID#	Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

~~cant obtained the data from another firm (identify); applicant copied data from a publication; applicant obtained a copy of the data from EPA).~~

~~(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:~~

~~(1) The data the applicant has submitted to EPA under paragraph (b) of this section;~~

~~(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and~~

~~(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.~~

~~(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:~~

~~(1) A notification of the applicant's intent to apply for registration, including the proposed product name;~~

~~(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);~~

~~(3) An identification of the item(s) of data to which the offer applies;~~

~~(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and~~

~~(5) The applicant's name, address, and telephone number.~~

~~(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:~~

~~(1) All data submitted or specifically cited by the applicant in support of the registration; and~~

~~(2) Each other item of data in the Agency's files which:~~

~~(i) Concerns the properties or effects of any such active ingredient; and~~

~~(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.~~

~~(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)~~

~~[44 FR 27953, May 11, 1979]~~

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2. thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumplacement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapor: [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate. precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

~~§ 162.11 Criteria for determinations of unreasonable adverse effects.~~

~~(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing*—(1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five~~

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . . ," "Distributed by. . . ," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following heading of directions for use		
10A	Reentry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D	Directions for use	All products	None	None	May be in metric as well as U.S. units

Appendix IV-3

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

Appendix IV-4

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	6 point
Above 10 to 15	8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

Appendix IV-4
(continued)

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List) Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
    (disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List) Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

"Toxic" Commercial Pesticide Products (RCRA "F" List) Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
    (kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List) Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

Appendix IV-4
(continued)

"Toxic" Commercial Pesticide Products (RCRA "F" List) Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®)
Vinyl chloride
Xylene